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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/575,047

04/04/2006

Wladimir Hogenhuis

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210 7590 08/26/2008  
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EXAMINER

KASTURI, SRIRAM

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

08/26/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/575,047	<b>Applicant(s)</b> HOGENHUIS ET AL.	
	<b>Examiner</b> SRIRAM KASTURI	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4-4-06</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1-10 are pending.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by teachings of Li et al (US Pubno.US2002/0022637 A1).

Li et al teach tetrahydroisoquinoline analogs useful as growth hormone secretagogues, which are useful in stimulating endogenous production or release of growth hormone (Abstract). Their growth hormone secretagogues stimulate release of endogenous growth hormone and thus have similar effects or uses as growth hormone itself, these effects are varied and multitudinous disorders (Page 24, paragraph 0116, lines 1-6). Their teachings include use of their growth hormone secretagogues alone or in combination with other growth hormone secretagogues or other suitable therapeutic agents useful in the treatment of various diseases including anti-diabetic agents (Page 26, paragraph 0121 lines 1-3) dipeptidyl peptidase IV (DP4) inhibitor (Page 26, paragraph 0122, line 14). Thus the combination of growth hormone secretagogue and DP4 is expected to result in the increased efficacy for the treatment of diabetes which is one of the growth hormone related disorders. Therefore it is obvious that the

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combination of growth hormone secretagogue and DP4 will result in increased growth hormone levels compared to secretagogue alone.

Their growth hormone secretagogues can be administered to various commercially important animals such as swine, cattle, sheep and the like (Page 24, paragraph 0109, lines 3-5) and to other mammalian species, such as monkeys, dogs, cats, rats, humans etc., in need of treatment (Page 25, paragraph 0118, lines 1-4). They also teach use of these growth hormone secretagogues for the maintenance of muscle strength and function in elderly humans (Page 24, paragraph 0113, lines 7 and 8). As the combination of growth hormone secretagogue and DP4 will result in increased growth hormone levels in the body of the mammal, will also increase growth hormone levels in plasma. Thus resulting an elevation in the plasma concentration of growth hormone.

Their teachings include use of suitable anti-diabetic agents for use in combination with tetrahydroisoquinoline growth hormone secretagogues including dipeptidyl peptidase IV (DP4) inhibitors (Page 26, paragraph 0122, line 14). Their teachings include growth hormone deficiency related diseases: growth retardation (Page 25, paragraph 0116, lines 20) metabolic syndrome or metabolic disorder (Page 25, paragraph 0117, line 2) injury, trauma, burn a wound in need of healing or a patient recovering from surgery (Page 25, paragraph 0116, lines 14,15, 37, 53, 54). Li et al teach a pharmaceutical composition comprising their active ingredient which is growth hormone secretagogue in association with pharmaceutical carrier comprising a growth promoting agent like DP4 (Page 24, paragraph 0110 lines 1-5). Thus Li et al teach a

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combination of growth hormone secretagogue and DP4 for the treatment of growth hormone related disorders including diabetes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SRIRAM KASTURI whose telephone number is (571)270-5263. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sriram Kasturi/  
Examiner

/Gollamudi S Kishore, Ph.D/

Primary Examiner, Art Unit 1612

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